

## General

#### Guideline Title

ACR Appropriateness Criteria® suspected liver metastases.

## Bibliographic Source(s)

Blake MA, McDermott S, Rosen MP, Baker ME, Fidler JL, Greene FL, Harrison SA, Hindman NM, Katz DS, Lalani T, Miller FH, Small WC, Sudakoff GS, Tulchinsky M, Yaghmai V, Yee J, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® suspected liver metastases. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 9 p. [48 references]

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Heiken JP, Bree RL, Rosen MP, Foley WD, Gay SB, Grant TH, Huprich JE, Lalani T, Miller FH, Sudakoff GS, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® suspected liver metastasis. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 8 p.

The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

## Recommendations

## Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Suspected Liver Metastases

<u>Variant 1</u>: Initial imaging test following detection of primary tumor.

Radiologic Procedure	Rating	Comments	RRL*
Rating Sealer Will Comply not appropriat	e; 84,5,6 May be appropriate;	718. Ageisually applied rate ing portal venous phase (PVP). Hepatic arterial phase (HAP) imaging is useful for patients with a hypervascular primary tumor such	*Relative Radiation Level
		as (but not limited to) renal cell, pancreatic islet cell, and thyroid carcinoma; carcinoid and other neuroendocrine tumors; and melanoma.	

Radiologic Procedure MRI abdomen without and with	Rating	Comments Dynamic gadolinium-chelate-enhanced imaging is used	RRL*
contrast		most commonly. Delayed imaging after iron oxide or gadolinium-based hepatobiliary contrast agents (e.g., BOPTA or gadoxetic acid) can be useful for staging patients with liver metastases. See statement regarding contrast in the text below under "Anticipated Exceptions."	
FDG-PET/CT skull base to mid-thigh	7	When the primary tumor is known to be FDG-PET avid. May be particularly valuable if liver-directed therapy is planned. Whole-body PET can be done for primaries like melanoma or sarcoma.	
MRI abdomen without contrast	5	When GFR precludes contrast, T2 and DWI can be done to exclude metastases.	О
CT abdomen without and with contrast	5	Noncontrast study useful if metastases are calcified/hemorrhagic but does add radiation dose.	
CT abdomen without contrast	4	CT of the abdomen without contrast is potentially indicated if patients cannot receive iodinated contrast and/or gadolinium, and/or cannot undergo MRI.	
US abdomen	4	Doppler may be useful, particularly in vascular lesions.	О
CTA abdomen with contrast	2	Only for operative planning – not for diagnosis of metastases.	
In-111 somatostatin receptor scintigraphy	2	May be useful in patients with neuroendocrine tumors.	
Rating Scale: 1,2,3 Usually not appropria	tte; 4,5,6 May be ap	opropriate; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 2</u>: Surveillance following treatment of primary tumor.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen with contrast	8	Images are acquired during PVP. HAP imaging is useful for patients with a hypervascular primary tumor such as (but not limited to) renal cell, pancreatic islet cell, and thyroid carcinoma; carcinoid and other neuroendocrine tumors; and melanoma.	
Ming Schale in , 2, ith bist all devitappropriate contrast	e;&,5,6 May be appropriate;	7 [3] Advision by depining right late-enhanced imaging is used most commonly. Delayed imaging after iron oxide or gadolinium-based hepatobiliary contrast agents (e.g., BOPTA or gadoxetic acid) can be useful for staging	©Relative Radiation Level

Radiologic Procedure	Rating	patients with liver metastases. See statement regarding contrast in the text below under "Anticipated	RRL*
		Exceptions."	
FDG-PET/CT skull base to mid-thigh	7	When the primary tumor is known to be FDG-PET avid. May be particularly valuable if liver-directed therapy is planned. Whole-body PET can be done for primaries like melanoma or sarcoma.	
MRI abdomen without contrast	5	When GFR precludes contrast, T2 and DWI can be done to exclude metastases.	О
CT abdomen without and with contrast	5	Noncontrast study useful if metastases are calcified/hemorrhagic but does add radiation dose.	
CT abdomen without contrast	4	CT of the abdomen without contrast is potentially indicated if patients cannot receive iodinated contrast and/or gadolinium, and/or cannot undergo MRI.	
US abdomen	4	Doppler may be useful, particularly in vascular lesions.	О
In-111 somatostatin receptor scintigraphy	4	May be useful in patients with neuroendocrine tumors.	
CTA abdomen with contrast	2	Only for operative planning – not for diagnosis of metastases.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 3</u>: Abnormal surveillance US, CT, or MRI, in PVP: high suspicion of malignancy.

Radiologic Procedure	Rating	Comments	RRL*
MRI abdomen without and with contrast	9	Dynamic gadolinium-chelate-enhanced imaging is used most commonly. Delayed imaging after iron oxide or gadolinium-based hepatobiliary contrast agents (e.g., BOPTA or gadoxetic acid) can be useful for staging patients with liver metastases. See statement regarding contrast in text under "Anticipated Exceptions."	O
Percutaneous biopsy liver	8		Varies
CT abdomen with contrast	8	Images are acquired during PVP. HAP imaging is useful for patients with a hypervascular primary tumor such as (but not limited to) renal cell, pancreatic islet cell, and thyroid carcinoma; carcinoid and other neuroendocrine tumors; and melanoma.	
Raing Scale: T. skáll Usasellyonoid upjedpria	te; 74,5,6 May be appropriate;	7, W. Del shelly impropriate is known to be FDG-PET	*Relative

Radiologic Procedure	Rating	avid. May be particularly valuable if liver-directed therapy is planned. Whole-body PET can be done for	RRL*
		primaries like melanoma or sarcoma.	
MRI abdomen without contrast	5	When GFR precludes contrast, T2 and DWI can be done to exclude metastases.	
CT abdomen without and with contrast	5	Noncontrast study useful if metastases are calcified/hemorrhagic but does add radiation dose.	
US abdomen	4	Doppler may be useful, particularly in vascular lesions.	0
US abdomen intraoperative/laparoscopic	4		О
In-111 somatostatin receptor scintigraphy	3	May be useful in patients with neuroendocrine tumors.	
CTA abdomen with contrast	3	Only for operative planningnot for diagnosis of metastases.	
CT abdomen without contrast	3	CT of the abdomen without contrast is potentially indicated if patients cannot receive iodinated contrast and/or gadolinium, and/or cannot undergo MRI.	
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 4</u>: Abnormal surveillance US, CT, or MRI in PVP suggests but is not definitive for benign lesion(s).

Radiologic Procedure	Rating	Comments	RRL*
MRI abdomen without and with contrast	9	Dynamic gadolinium-chelate-enhanced imaging is used most commonly. Delayed imaging after iron oxide or gadolinium-based hepatobiliary contrast agents (e.g., BOPTA or gadoxetic acid) can be useful for staging patients with liver metastases. See statement regarding contrast in text under "Anticipated Exceptions."	0
CT abdomen with contrast	8	Images are acquired during PVP. HAP imaging is useful for patients with a hypervascular primary tumor such as (but not limited to) renal cell, pancreatic islet cell, and thyroid carcinoma; carcinoid and other neuroendocrine tumors; and melanoma.	
MRI abdomen without contrast	5	When GFR precludes contrast, T2 and DWI can be done to exclude metastases.	О
Rating Soulen Walfold studywich copprag	riate; 54,5,6 May be appropriate;	7.8. On Community appropriated if metastases are calcified/hemorrhagic but does add radiation dose.	*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
Percutaneous biopsy liver	4		Varies
US abdomen	4	Doppler may be useful, particularly in vascular lesions.	О
FDG-PET/CT skull base to mid-thigh	4	When the primary tumor is known to be FDG-PET avid. Depends on the lesion and what prior imaging has shown. See the NGC summary ACR Appropriateness Criteria® liver lesion — initial characterization. Whole body PET can be done for primaries like melanoma or sarcoma.	
In-111 somatostatin receptor scintigraphy	3	May be useful in patients with neuroendocrine tumors.	
CTA abdomen with contrast	3	Only for operative planningnot for diagnosis of metastases.	
US abdomen intraoperative/laparoscopic	3		О
CT abdomen without contrast	3	CT abdomen without contrast is potentially indicated if patients cannot receive iodinated contrast and/or gadolinium, and/or cannot undergo MRI.	
Rating Scale: 1,2,3 Usually not appropri	ate; 4,5,6 May be appropriate	te; 7,8,9 Usually appropriate	*Relative Radiation Level

#### Summary of Literature Review

In the United States, metastatic disease is the most common cause of malignancy in the liver and is 20 to 50 times more common than primary liver cancer. The colon, stomach, pancreas, and breast are the most common primary sites. The appearance of a new lesion in the liver in a patient with a history of cancer strongly suggests hepatic metastasis. On the other hand, most small ( $\leq$ 1-1.5 cm) liver lesions, even in patients with known malignancy, are not malignant, especially if there are fewer than five lesions. The American College of Radiology (ACR) has recently published a white paper on the management of incidental findings on abdominal CT. In most series, about one-third of patients who die with a malignancy have liver involvement.

The liver is susceptible to metastatic disease, primarily due to the nature of the endothelial lining. The dual blood supply to the liver has an effect on the vascularity of liver metastases, with those supplied by the hepatic arterial system being more vascular than those supplied by the portal venous system. Most gastrointestinal cancer is spread through the portal venous system, whereas other tumors are spread through the hepatic arterial system.

Numerous imaging methods are available for detecting intrahepatic metastatic disease before, during, and after definitive therapy for the primary lesion. The usefulness of various imaging tests can vary significantly across institutions because of local radiological expertise, availability of equipment or personnel, and the wishes and biases of treating physicians and radiologists.

This document reviews the broad variety of available imaging tests so that each can be rated by the expert panel, realizing that many published scientific studies do not compare all imaging tests at the current state of the art.

#### Ultrasound

Ultrasound (US) is the most available technique for liver imaging worldwide, and in many countries is the major imaging test used to search for liver metastases. In the United States, the widespread availability of computed tomography (CT) and magnetic resonance imaging (MRI), the relatively higher dependence of US on operator skill, and the limited availability of US contrast agents contribute to a lesser role for US diagnosis. In the United States pretreatment and post-treatment screening for metastases is performed infrequently with US. Comparative studies demonstrate that unenhanced gray-scale US has high specificity but lower sensitivity than CT and MRI. With US, metastases can be hypoechoic, hyperechoic, cystic, or diffuse. Doppler may be useful, particularly in vascular lesions such as neuroendocrine tumors and sarcomas.

Research on current US contrast agents has demonstrated high accuracy in characterizing liver lesions. The second-generation agents generally consist of either stable perfluorocarbon or sulphur hexafluoride-containing microbubbles which are injected intravenously and insonated with low acoustic pressure. The particle then emits a harmonic signal and can be detected with pulse inversion recovery to show the vascular architecture of a lesion and temporal course of enhancement and thereby help characterize the lesion. These second-generation agents, however, have not yet been approved for hepatic imaging in the United States.

In patients with lesions which are suspicious for malignancy, percutaneous biopsy, under either US or CT guidance, may be appropriate as clinically indicated.

#### Intraoperative/Laparoscopic Ultrasound

Intraoperative ultrasound (IOUS) is the most accurate imaging technique for detecting liver metastases at the time of primary tumor resection or resection of previously identified hepatic metastases. It is complementary to surgical inspection and palpation. Additionally, IOUS can be important for localization of tumors for ablative techniques or to guide intraoperative biopsy or surgical resection.

Laparoscopic US (LUS), an alternative to open IOUS, has shown promising results. In one study of 55 patients with primary and secondary liver neoplasms who underwent LUS as part of a tumor ablation procedure, LUS demonstrated all 201 liver tumors shown by triphasic CT and an additional 21 lesions not shown by CT.

Endoscopic US (EUS) has emerged as an alternative tool for imaging the liver. In one study the diagnostic accuracies of EUS with or without fine-needle aspiration (FNA) and CT were 98% and 92%, respectively. However, in this study the CT collimation was suboptimal at 10 mm, and the study authors acknowledged that EUS/EUS-FNA has some limitations in examining the right hepatic lobe.

#### Computed Tomography

CT is particularly suited for evaluating metastatic disease, because the liver and potential extrahepatic sites of tumor spread can be evaluated during the same examination. Multidetector helical CT (MDCT) is the preferred examination in the United States for surveillance for metastatic disease after treatment of the primary neoplasm. Because most hepatic metastases are relatively hypovascular compared with normal liver parenchyma, the lesions are hypoattenuating when imaged during the peak of hepatic parenchymal enhancement (portal venous phase [PVP]). In general, therefore, imaging during the PVP of hepatic enhancement is adequate to detect most hepatic lesions in most patients.

Hypervascular lesions are less common, and tumors in this group include metastases from renal cell carcinoma, carcinoid tumor, islet cell carcinoma, thyroid carcinoma, melanoma, and neuroendocrine tumors. In a large series of patients, small (<2 cm) hypervascular lesions were seen better in the arterial phase than in the PVP. With the widespread use of multidetector scanners, arterial phase scanning can be routine. Although metastases from breast carcinoma are sometimes hypervascular, two studies showed that arterial phase imaging was not necessary in this group. Hypervascular lesions may be isoattenuating to liver during the PVP of hepatic enhancement. With helical CT, both arterial and PVP imaging are recommended for patients with hypervascular primary tumors. Noncontrast images (or virtual noncontrast images if dual-energy CT is used) are occasionally helpful for lesions with hemorrhage or calcification (e.g., melanoma, mucinous metastases). However, in younger patients with curable disease, the radiation exposure must be balanced against the potentially increased yield obtained by doing multiphasic CT.

CT arterial portography is almost never used at present, as it is an invasive angiographic technique that often yields artifacts that decrease accuracy. CT angiography (CTA) is no longer used for diagnostic purposes and is rarely used for preoperative planning.

#### Magnetic Resonance Imaging

With MRI, most hepatic metastases are hypointense to normal liver on T1-weighted images and hyperintense to liver on T2-weighted images. Morphologic, signal intensity, and contrast enhancement features have been shown to be useful in distinguishing metastatic lesions from common benign lesions such as hemangiomas and cysts.

Contrast-enhanced imaging is an important part of the hepatic MRI examination for detecting metastases and is particularly useful in characterizing hepatic lesions that are identified. Gadolinium chelates, which are the most widely used MR contrast agents, are most useful when used with dynamic T1-weighted gradient echo sequences. Comparative studies have shown gadolinium-enhanced MRI to be more sensitive in the detection

of liver metastases than positron emission tomography (PET) and PET/CT. Gadolinium ethoxybenzyl diethylenetriaminepentaacetic acid (gadoxetic acid disodium or Gd-EOB-DTPA) is a more recently developed liver-specific contrast agent with combined perfusion and hepatocyte-selective properties. A comparative study demonstrated a superior detection rate and higher confidence in characterization of liver metastases for Gd-EOB-DTPA-enhanced MRI than for PET/CT. MRI using superparamagnetic iron oxide (SPIO) contrast agents, which are taken up selectively by the reticuloendothelial system, has been shown to be more sensitive than unenhanced MRI and equal to or more sensitive than gadolinium-enhanced MRI. In one study iron-oxide-enhanced MRI also was more sensitive than 16-row MDCT for detecting liver metastases. Another study demonstrated that iron-oxide-enhanced MRI was more sensitive but less specific than PET in detecting liver metastases. In one study, gadoxetic acid showed comparable diagnostic performance to iron-oxide-enhanced MRI for detecting liver metastases. Delayed-phase imaging during gadobenate dimeglumine (Gd-BOPTA)-enhanced MRI and mangafodipir trisodium (Mn-DPDP)-enhanced MRI have been shown to be equivalent to iron-oxide-enhanced MRI for detecting liver metastases, but mangafodipir and SPIO are currently not available in the United States. In another study Mn-DPDP MRI proved to be superior to PET/CT in detecting small liver metastases.

#### Nuclear Imaging

PET has become more widely used in detecting metastatic disease. Two meta-analyses comparing CT, MRI, and fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) PET in patients with cancers of the gastrointestinal tract concluded that FDG-PET is the most sensitive imaging test for distinguishing hepatic metastases from colorectal cancer. In addition, several studies have demonstrated that the addition of FDG-PET to a conventional staging evaluation in colorectal cancer patients with potentially resectable liver metastases results in a change in management of 20% to 32%, mainly due to detection of unknown extrahepatic disease. PET also has been shown to be accurate in distinguishing benign from malignant liver tumors. A limitation of FDG-PET, however, is that it may fail to demonstrate small (<1 cm) liver metastases. In addition, the sensitivity of FDG-PET for demonstrating hepatic metastases from colorectal cancer is reduced in patients who have undergone recent chemotherapy. One study demonstrated that acquisition of delayed images improved the hepatic detection of pathological FDG uptake. For staging and restaging patients with colorectal liver metastases, integration of CT and FDG-PET data, either by fusion or by integrated PET/CT imaging, enables better management guidance than with either technique alone. PET/CT has been shown to have high sensitivity and specificity for the presence of liver metastases, and this capability has been well documented in patients with colorectal cancer.

Traditional reticuloendothelial radionuclide imaging is no longer used for detecting liver metastases. Somatostatin receptor scintigraphy is capable of demonstrating hepatic metastases from endocrine tumors but is not as sensitive as CT and MRI.

#### Summary

- Many radiologic techniques are available for preoperative detection of liver metastases and postoperative surveillance.
- Some of the less widely used screening techniques can be useful when there is a need for specific problem solving.
- Rapid technological and clinical advances in equipment, contrast agents, and radioisotopes make direct comparison of the various techniques difficult.
- In addition, local custom and equipment availability within communities or medical centers can be expected to lead to a variety of indications
  and applications in detecting hepatic metastatic disease.

#### Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

#### Abbreviations

- CT, computed tomography
- CTA, computed tomography angiography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography
- BOPTA, gadobenate dimeglumine
- HAP, hepatic arterial phase
- In, indium
- MRI, magnetic resonance imaging

- PVP, portal venous phase
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range		
O	0 mSv	0 mSv		
	<0.1 mSv	<0.03 mSv		
	0.1-1 mSv	0.03-0.3 mSv		
	1-10 mSv	0.3-3 mSv		
	10-30 mSv	3-10 mSv		
	30-100 mSv	10-30 mSv		
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a				

<sup>\*</sup>RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".

## Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

# Scope

## Disease/Condition(s)

Liver metastases

# Guideline Category

Diagnosis

Evaluation

# Clinical Specialty

Gastroenterology

Internal Medicine

Nuclear Medicine

Oncology

Radiology

## **Intended Users**

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

## Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for patients with suspected liver metastases

## **Target Population**

Patients with suspected liver metastases

#### **Interventions and Practices Considered**

- 1. Computed tomography (CT) abdomen
  - With contrast
  - Without contrast
  - Without and with contrast
- 2. CT angiography (CTA) abdomen with contrast
- 3. Magnetic resonance imaging (MRI) abdomen
  - Without and with contrast
  - Without contrast
- 4. Fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography (FDG-PET)/CT skull base to mid-thigh
- 5. Ultrasound (US)
  - Abdomen
  - Abdomen intraoperative/laparoscopic
- 6. Indium (In)-111 somatostatin receptor scintigraphy
- 7. Percutaneous liver biopsy

## Major Outcomes Considered

Utility of radiologic examinations in diagnosis and evaluation of suspected liver metastases

# Methodology

#### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology

Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

#### Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

- Category 1 The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the American College of Radiology (ACR) Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

#### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

#### Potential Harms

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

#### Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

# **Qualifying Statements**

## **Qualifying Statements**

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

## Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

#### **IOM Domain**

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

Blake MA, McDermott S, Rosen MP, Baker ME, Fidler JL, Greene FL, Harrison SA, Hindman NM, Katz DS, Lalani T, Miller FH, Small WC, Sudakoff GS, Tulchinsky M, Yaghmai V, Yee J, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® suspected liver metastases. [online publication]. Reston (VA): American College of Radiology (ACR); 2011. 9 p. [48 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

1998 (revised 2011)

## Guideline Developer(s)

American College of Radiology - Medical Specialty Society

## Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

#### Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Gastrointestinal Imaging

## Composition of Group That Authored the Guideline

Panel Members: Michael A. Blake, MB, BCh (*Principal Author and Panel Vice-chair*); Shaunagh McDermott, MD (*Research Author*); Max Paul Rosen, MD, MPH (*Panel Chair*); Mark E. Baker, MD; Jeff L. Fidler, MD; Frederick L. Greene, MD; Stephen A. Harrison, MD; Nicole M. Hindman, MD; Douglas S. Katz, MD; Tasneem Lalani, MD; Frank H. Miller, MD; William C. Small, MD, PhD; Gary S. Sudakoff, MD; Mark Tulchinsky, MD; Vahid Yaghmai, MD, MS; Judy Yee, MD

#### Financial Disclosures/Conflicts of Interest

#### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Heiken JP, Bree RL, Rosen MP, Foley WD, Gay SB, Grant TH, Huprich JE, Lalani T, Miller FH, Sudakoff GS, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® suspected liver metastasis. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 8 p.

The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

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Electronic copies: Available from the American College of Radiology (ACR) Web site

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

## Availability of Companion Documents

The following are available:

	ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable
	Document Format (PDF) from the American College of Radiology (ACR) Web site
•	ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies:
	Available in Portable Document Format (PDF) from the ACR Web site
•	ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013
	Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site
•	ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic
	copies: Available in Portable Document Format (PDF) from the ACR Web site
•	ACR Appropriateness Criteria® Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies:
	Available in PDF from the ACR Web site
•	ACR Appropriateness Criteria® suspected liver metastases. Evidence table. Reston (VA): American College of Radiology; 2011. 13 p.
	Electronic copies: Available from the ACR Web site

#### Patient Resources

None available

#### **NGC Status**

This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This NGC summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 23, 2009. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on August 18, 2011.

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